REDACTED VERSION – PUBLICLY FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LIMITED,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED,

Defendants.

Civil Action No. 04-171

CONFIDENTIAL
FILED UNDER SEAL

TEVA'S OPENING BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT

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Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.

Dated: June 30, 2006

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I. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDING

Glaxo owns a patent covering the use of ethanol to stabilize oral solutions of ranitidine.[1] Ranitidine is a chemical compound that belongs to a class of drugs commonly referred to as histamine type 2 (H_2) receptor antagonists (or H_2 antagonists or H_2 blockers). Ranitidine halts the chemical reaction that causes the production of acid in the stomach and, therefore, ranitidine is used to treat those who suffer from various gastro-esophageal disorders relating to the production of excessive gastric acid. Teva seeks to introduce a generic version of Glaxo's oral ranitidine solution.

Before Teva can sell its generic formulation, Teva must submit an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("the FDA") for approval.[2] Because Glaxo has reported to the FDA that its Zantac® oral solution is covered by U.S. Patent No. 5,068,249 (hereinafter "the '249 patent"), Teva certified in its ANDA that Glaxo's patent "will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."[3] In compliance with the Hatch-Waxman Act, Teva also provided Glaxo with notice of its certification.[4]

As a result of Teva's notice, Glaxo brought this action, alleging infringement of the '249 patent.[5] In this suit, Glaxo concedes that the '249 patent claims do not literally cover Teva's ranitidine oral solution because the claims require the inclusion of ethanol while Teva's formulation does not include ethanol. Teva's formulation includes **Redacted** rather than ethanol. For its part, Teva has admitted that its formulation has all of the elements of the claims of the '249 patent except: 1) "a stabilizing effective amount of;" 2) "ethanol;" 3) "2.5% to 10% weight/volume ethanol;" and 4) "7% to 8% weight/volume ethanol."

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[1] The brand name for ranitidine is Zantac®.
[2] *See* 21 U.S.C. § 355(j).
[3] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).
[4] *See* 21 U.S.C. § 355(j)(2)(B).
[5] *See* 21 U.S.C. § 355(j)(5)(B)(iii).

Teva can only infringe the '249 patent, if at all, under the doctrine of equivalents. Teva's motion for summary judgment is concerned with only one of the four claim elements at issue, the claim element "ethanol."

In accordance with the Scheduling Order, Teva respectfully moves for summary judgment, seeking judgment as a matter of law that Teva's ranitidine formulation does not infringe the claims of the '249 patent. Judgment as a matter of law is appropriate because "ethanol" in the claims of the '249 patent can have no range of equivalents beyond "ethanol." Even if some range of equivalents would be appropriate, Glaxo has failed to prove that the **Redacted** in Teva's formulation performs all of the functions that ethanol performs in Glaxo's ranitidine formulation. This is an essential element of Glaxo's proof, and it is lacking in this case.

II. SUMMARY OF THE ARGUMENT

Teva asks this Court to rule that Glaxo cannot use the doctrine of equivalents to broaden the scope of its patent to cover a formulation that it did not disclose or claim. The undisputed record establishes that Glaxo experimented with the use of **Redacted** in its ranitidine formulation months before it filed its first patent application. Glaxo also foresaw its use as a stabilizer for the ranitidine. Nonetheless, Glaxo did not disclose or claim the use of **Redacted** in its patent. Glaxo only disclosed and claimed ethanol. In fact, to convince the Patent Office that it had invented anything at all, Glaxo presented laboratory experiments only showing that ethanol resulted in a surprising increase in the stability (or shelf life) of its formulation. Glaxo argued that "only by the present invention" would one of ordinary skill in the art recognize the stabilizing benefits of ethanol. By disclosing, claiming and arguing only ethanol above all other available commonly known excipients, Glaxo clearly delineated the scope of its invention to the use of ethanol to increase the stability of a ranitidine oral solution and nothing else.

Five legal doctrines prevent Glaxo from relying on the doctrine of equivalents to expand the claims of the '249 patent beyond the disclosed and claimed "ethanol." First, arguments made

by a patentee to obtain the patent bar expansion of his claims. *See Tanabe Seiyaku Co. Ltd v. ITC*, 109 F.3d 726 (Fed. Cir. 1997) Second, prosecution history estoppel bars a patentee from expanding the scope of his patent claims to include subject matter surrendered by amendment during prosecution of his patent. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002). Third, the doctrine of equivalents does not allow a patentee to vitiate claim limitations in an equivalents analysis. *See Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998). Fourth, this case is analogous to cases on waiver and dedication to the public. A patentee waives the right to recapture subject matter that was disclosed, but not claimed, in his patent. *See Johnson & Johnston Assocs. Inc. v. R.E. Service Co.*, 285 F.3d 1046 (Fed. Cir. 2002). Fifth, a claim should be interpreted to be valid, if possible. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 749 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988). If expanding a claim under the doctrine of equivalents would render the claim invalid under 35 U.S.C. § 112, that interpretation is improper. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005)("In light of the statutory directive that the inventor provide a "full" and "exact" description of the claimed invention, the specification necessarily informs the proper construction of the claims.").

Even if the Court determines that the patent claims are entitled to some range of equivalents, Glaxo still must prove that **Redacted** performs the same function, in the same way, to achieve the same results as the ethanol in its formulation. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.* 339 U.S. 605, 608, 94 L. Ed. 1097, 70 S. Ct. 854 (1950). Ethanol performs **Redacted** in Glaxo's formula: **Redacted**

(Exhibit 1 at A002,[6] Anderson Rpt., March 16, 2006, ¶ 40) Glaxo has no proof on functions 1 and 2 and, therefore, it has failed to meet its burden of proof under the doctrine of equivalents.

[6] As used in this brief, references to "Exhibit" are to the Exhibits attached to the Appendix supporting Teva's Motion In Summary Judgment of Non-Infringement, filed herewith.

Glaxo cannot, as a matter of law, claim that Teva's Redacted formulation is equivalent to its ethanol formulation. Such a result would fundamentally violate several doctrines of patent law, all of which follow from the premise that the Patent Office should be the first arbiter of the patentability of foreseeable equivalents of an invention. A patentee must present the full range of his invention for examination in the Patent Office or he will lose what he has not subjected to examination. Indeed, as between "a patentee who had a clear opportunity to negotiate broader claims but did not do so, and the public at large, it is the patentee who must bear the cost of its failure to seek protection for [a] foreseeable alteration of its claimed [invention]." *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420, 1426 (Fed. Cir. 1997).

III. STATEMENT OF THE FACTS

The doctrine of equivalents should not be used to broaden the scope of Glaxo's patent claims to capture Redacted because Glaxo foresaw, but did not disclose or claim, the use of Redacted as a stabilizer for ranitidine. Glaxo only disclosed and convinced the Patent Office that ethanol provided the surprising results that distinguished it from the prior art. Any other holding would distort the principles of fairness and equity that underlie the doctrine of equivalents. A patentee should only be allowed to capture subject matter that was unforeseeable to the inventor at the time of the invention and insubstantial in comparison to the corresponding claim limitation. *See Festo Corp. v. Shoketsu Kinzoku*, 535 U.S. 722, 741 (2002). That is not the case here. As explained below, the use of Redacted as a stabilizer for ranitidine was foreseen by Dr. Long, the inventor. Indeed, he even recorded his knowledge in a notebook.

A. Teva's Formulation Uses Redacted

The original formulation work for the accused oral ranitidine solution was performed by Novopharm Limited of Canada. (Exhibit 2 at A007-A009; Exhibit 3 at A010). In April 2000, Teva acquired Novopharm, adopted Novopharm's research on that oral ranitidine solution, and modified it to comport with Teva's pharmaceutical research equipment and protocols. (Exhibit 2

at A008. The stated objectives for the ranitidine oral solution were two-fold.

Redacted

(Exhibit 4 at A012; Exhibit 5 at A015-A016).

To accomplish these objectives, Novopharm consulted "published information" for Glaxo's product, including the '249 patent. (Exhibit 4 at A012-A013). After analyzing that information, Novopharm decided that it should avoid Redacted in view of the claims of the '249 patent and *Id.* Novopharm, therefore, took affirmative steps to design around the '249 patent and make a non-infringing formulation.

Teva's oral ranitidine product has the following formula:

Redacted

(Exhibit 7 at A017). Teva's formulation uses Redacted

B. Glaxo's Formulation Uses Ethanol

Glaxo's ranitidine oral solution has the following formula:

Ingredient	Quantity per 1 mL
Redacted	

[7] pH also stabilizes ranitidine and Glaxo had a patent covering that as well, U.S. Pat. No. 4,585,790 to Padfield. It has expired, however, and the public is free to use that technology. (Exhibit 6 at A023-24) (Response to Request to Admit No. 114).

Redacted

(Exhibit 1 at A004, Anderson Report, March 16, 2006, ¶ 52). Glaxo's formulation uses ethanol.

C. Glaxo's Patent Claims

The '249 patent contains 12 claims. Claims 1 and 11 are independent. They are as follows:

> 1. A pharmaceutical composition which is an aqueous formulation for oral administration of an effective amount of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation comprising a stabilizing effective amount of ethanol and said composition having a pH in the range of 6.5-7.5.
>
> 11. A pharmaceutical composition which is an aqueous formulation of ranitidine suitable for oral administration containing 150 mg ranitidine per 10 ml dose expressed as freebase, said formulation having a pH in the range 7.0 to 7.3 and also containing 7% to 8% weight/volume ethanol based on the complete formulation.

(Col. 2, line 67 - Col. 3, line 4; Col. 4, lines 10-16)(emphasis added). Each claim of the '249 patent requires the inclusion of ethanol in the formulation.

D. A Comparison Between Teva's Formulation And The Claims Of The '249 Patent

For purposes of this motion, the difference between Teva's formulation and the claims of the '249 patent is that Teva's formulation does not contain ethanol. Rather, it contains Redacted

Glaxo has admitted that Teva's formulation does not literally infringe the claims of the '249 patent.[8]

[8] (Exhibit 6 at A019) (Glaxo Response to Request for Admission No. 87).

E. The Development Of Glaxo's Formulation

Beginning in the early 1980s, Glaxo began developing a ranitidine oral solution, i.e., Zantac® syrup. *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265, 277 (D. Md. 1998).[9] The original formulation was based on an earlier Zantac® solution for injectable use. *Id.* (Exhibit 8 at A034-36, Long Tr. at pp. 277-79).[10] In November 1983, Glaxo submitted a "Notice of Claimed Investigational Exemption for a New Drug for Zantac® (ranitidine hydrochloride) Syrup" to the FDA. *Id.* (Exhibit 8 at A033, Long Tr. at p. 276). As described in its November 1983 FDA notice, the original formulation for Zantac® oral solution included a preservative system composed of three preservatives, but it did not contain any ethanol. *Pharmadyne*, 32 F. Supp. 2d at 277. Dr. Long noticed that there was a decrease in the concentration of one of the preservatives over time. *Pharmadyne* at 278.[11] He had the product analyzed by Glaxo microbiologists who discovered that the formulation was contaminated with a microbial contaminant called *Pseudomonas cepacia*. *Id.*[12] (Exhibit 8 at A 038, Long Tr. at p. 281).

To combat the microbial contamination problem, Dr. Long explored the use of Redacted as a preservative for the formulation, but it failed:

Redacted

(Exhibit 8 at A039-A041, Long. Tr. at 408-09; 445, lines 1-8); *Pharmadyne* at 278. Dr. Long's notebook from that time period shows the use of 2.5% Redacted did not eradicate the

[9] Teva cites to *Glaxo v. Pharmadyne* to establish basic facts that are not in dispute. As will be discussed later, the case is not binding precedent for this Court.
[10] Cites to "Long Tr." are to the trial transcript of the specific witness, i.e., inventor Long, in the *Glaxo v. Pharmadyne* bench trial. By stipulation and this Court's Order of May 12, 2006, this testimony is evidence in this case.
[11] *See* (Exhibit 6 at A020) (Glaxo Response to Request for Admission at p.14, No. 90).
[12] *See* (Exhibit 6 at A023) (Glaxo Response to Request for Admission at p.16, No. 93).

Pseudomonas cepacia or enhance the preserving power of the system. (Exhibit 9 at A042-A043). The notebook corroborates Dr. Long's testimony.

Dr. Long's notebook, however, also contains another entry by Dr. Long. In that entry, Dr. Long considered Redacted function as a stabilizer in an oral ranitidine solution, as opposed to a preservative. (Exhibit 10 at A045). As reproduced below, Dr. Long compared the Redacted for various properties, including stability, in July of 1985, before the first application for the '249 patent was filed:

Redacted

(Exhibit 10 at A045)(emphasis added). Dr. Long's notebook shows that he believed the Redacted *Id.* Importantly, Dr. Long also assessed both Redacted and ethanol's effect on the Redacted noting that Redacted was Redacted while ethanol was Redacted *Id.*

[13] The words preceding Dr. Long's notation are unclear. Whether Dr. Long wrote that Redacted effect on the Redacted was Redacted or that Redacted is immaterial to the undisputable fact that Dr. Long foresaw the use of Redacted as a stabilizer for ranitidine before his patent application was filed. *Id.* The fact that Dr. Long found that Redacted

Dr. Long's notebook confirms that he foresaw the use of Redacted as a stabilizer for ranitidine before he filed his first patent application on December 12, 1986.

F. Glaxo's '249 Patent Specification

Glaxo's '249 patent specification discloses nothing but ethanol to stabilize the ranitidine oral solution. Starting immediately with the Abstract, Glaxo claims that the invention is a formulation "enhanced by the addition of ethanol." (emphasis added). The title of the invention further emphasizes the use of ethanol: "AQUEOUS RANITIDINE COMPOSITION STABILIZED WITH ETHANOL." (emphasis added). In the Background of the Invention, Glaxo describes how it "surprisingly found that the stability of ranitidine in aqueous based formulations and more particularly aqueous based formulations for oral administration may be substantially enhanced by the addition of ethanol to the formulation." (Col. 1, lines 40-44) (emphasis added). Glaxo then describes the "present invention" as a pharmaceutical composition containing ranitidine, other components and "also containing ethanol." (Col. 1, lines 45-48) (emphasis added). The pharmaceutical composition will contain at least one conventional pharmaceutical excipient "in addition to the ethanol and ranitidine." (Col. 1, lines 50-52) (emphasis added). And again:

> The amount of ethanol present in the formulation is such that the resulting formulation has enhanced ability. Preferably the amount of ethanol in the composition on a weight-volume basis of the complete formulation is within the range of 2.5% to 10%, and more particularly is between 5% to 10% w/v, more especially 7-8% w/v.

(Col. 1, lines 54-60) (emphasis added).

The patent specification then states that, "the amount of ethanol in the formulation for oral administration, expressed as a percentage of the complete formulation on a weight/volume

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did not have antimicrobial (preservative) properties and abandoned it for that reason does not mean that it still would not stabilize ranitidine. "Antimicrobial properties" and "increased stability" are separate concepts. *See* Exhibit 1 at A002, Anderson Report, March 16, 2006, ¶ 40; Pharmadyne at 270-71 ("Glaxo rejected Redacted . . . as to its use as an agent against *pseudomonas cepacia,* not as an agent for stabilization.") The clear fact is that Dr. Long foresaw the use of Redacted as a stabilizer for ranitidine but did not disclose it in his patent application or claim it.

basis, is preferably within the range 2.5 to 10%, and more particularly between 5 to 10%, more especially 7-8%." (Col. 2, lines 30-34) (emphasis added). The patent specification also describes the process for preparing the formulation:

> The aqueous formulations for oral administration are conveniently prepared by mixing an aqueous solution of ranitidine and/or one or more of its physiologically acceptable salts together with ethanol and the excipients, with aqueous solution or dispersion of the viscosity-enhancing agent.

(Col. 2, lines 38-43) (emphasis added). Finally, the '249 patent ends with only one example, an example which contains 7.5% ethanol. (Col. 2, lines 53-65).

Interestingly, Glaxo described a number of other common pharmaceutical excipients that could be used in the formulation as alternatives. For each of those classes of excipients, Glaxo gave examples. For instance, Glaxo said that "examples of suitable preservatives include on[e] or more alkyl hydroxybenzoates such as methyl, ethyl, propyl and/or butyl hydroxybenzoates." (Col. 2, lines 12-13) (emphasis added). For viscosity enhancing agents, Glaxo said that examples "include Xanthan gum, sorbitol glycerol, sucrose, or a cellulose derivative such as carboxymethylcellulose or a salt thereof of a C_{1-4} alkyl and/or a hydroxy-C_{2-4} alkyl ether of cellulose such as methylcellulose, ethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxyethylmethylcellulose and hydroxypropylmethylcellulose." (Col. 2, lines 15-21). Glaxo provided examples of sweeteners: "sweeteners include saccharin sodium, sodium cyclamate, sorbitol and sucrose." (Col. 2, lines 22-23). Finally, Glaxo listed examples of flavoring agents: "flavouring agents include 'mint' flavours such as peppermint flavouring agents." (Col. 2, lines 24-25). Regarding the ethanol stabilizer, however, Glaxo provided no other examples or alternatives that could be used or that were contemplated. This suggests to one skilled in the art that only ethanol provides the claimed benefit of enhanced ranitidine stability. *See Tanabe Seiyaku Co. Ltd v. ITC*, 109 F.3d 726, 732 (Fed. Cir. 1997)(By describing a specific base-solvent combination instead of a class of ketone solvents, while also describing other reactants of the

claimed process by class, the specifically claimed combination suggests to a person skilled in the art that other ketones may not be useful for the reaction.)

The '249 patent specification contains no data to indicate how ethanol stabilizes ranitidine or how much stabilization is necessary. The patent only gives one formula and that formula contains only ethanol. Moreover, the patent specification describes only ethanol as the stabilizing agent and nothing more. Importantly, when other chemicals might be alternatives, the patent lists them. It lists them for preservatives, for viscosity enhancing agents, for sweeteners, and for flavoring. Notably, however, there are no alternatives listed for ethanol.

G. The Prosecution Of The '249 Patent

1. Overview

Glaxo filed the first patent application in a chain of patent applications that eventually led to the '249 patent on December 11, 1987, as USSN 07/131,442 ("the '442 application") entitled "Pharmaceutical Compositions." (G000236-237). [14] The '442 application claimed priority to a patent application filed in the United Kingdom on December 12, 1986, Serial Number 8,629,781. (G000246; G000249). The '442 application was abandoned in favor of application Serial No. 07/344,620 ("the '620 application"), which was filed on April 28, 1989. (G00111-112). The '620 application was continued as application Serial No. 07/494,804 ("the '804 application"), from which the '249 patent eventually issued. '249 patent, page 1.

Importantly, each of Glaxo's patent applications disclosed only ethanol as the excipient that gave the surprising increase in the stability of ranitidine. None of the applications suggested that it would be acceptable to substitute any other excipient for ethanol as a stabilizing agent. The applications also made no mention of Redacted as a stabilizer for ranitidine, even though Dr. Long had foreseen Redacted stabilizing effect on ranitidine before the first application was filed.

[14] File history documents, referenced herein as "G000111 through G000308" are attached as Exhibits 2 and 3 to the Joint Claim Construction Statement filed contemporaneously with this brief.

The first application (like each of the others) clearly states that the addition of ethanol is the invention:

> We have now surprisingly found that the stability of ranitidine in aqueous based formulations and more particularly aqueous based formulations for oral administration may be substantially enhanced by the addition of ethanol to the formulation.

(G000255)(emphasis added).[15]

2. The Details Of The Prosecution

On December 11, 1987, Glaxo filed U.S. Patent Application No. 07/131,442 (the '442 application). The specification in the '442 application is essentially the same as the application that ultimately issued as the '249 patent. The '442 application contained 14 claims. Two of those claims were independent, claims 1 and 13. They are as follows:

> 1. A pharmaceutical composition which is an aqueous formulation of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation also containing ethanol.
>
> 13. A pharmaceutical composition which is an aqueous formulation of ranitidine suitable for oral administration containing 150 mg ranitidine per 10 ml dose expressed as freebase, said formulation having a pH in the range 7.0 to 7.3 and also containing 7% to 8% weight/volume ethanol based on the complete formulation.

(G000243-244).

On May 5, 1988, the Examiner issued a rejection. (G000263). He rejected all 14 claims of the '442 application. *Id.* He rejected claims 1-10 as indefinite under 35 U.S.C. § 112, second paragraph. (G000264). The Examiner also rejected claims 1-12 under 35 U.S.C. § 112, first paragraph. *Id.* Finally, the Examiner rejected claims 1-14 as being obvious in light of the prior art under 35 U.S.C. § 103. The Examiner stated that "the art teaches the co-joining of ranitidine and an alcohol; e.g. ethanol." (G000265). "The addition of a non-critical pH limit and non-critical amounts are not seen as patentable limitations to the various claims." *Id.*

[15] The application also uses the terms "stability" and "shelf life" interchangeably. (G000254-255).

On November 7, 1988, Glaxo responded to the Examiner's rejection. It amended its claims to narrow the claim element "ethanol." It did so by requiring that the ethanol be present in a "stabilizing effective amount." The amendment was as follows:

> 1. (Amended) A pharmaceutical composition which is an aqueous formulation of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation also containing a stabilizing effect amount of ethanol and said composition having a pH in the range of 6.5 to 7.5.

(G000267).

Glaxo also cancelled claim 4. *Id.* Glaxo argued that because the claims had been amended, the 35 U.S.C. § 112, second paragraph, rejection had been eliminated. (G000268). Glaxo also argued that the claims were not obvious over the prior art. (G000268-269). The substance of those arguments are not relevant to this summary judgment motion.

On November 29, 1988, the Examiner again rejected all of the pending claims of the '442 application, claims 1-3 and 5-14. (G000271). The Examiner maintained his obviousness rejections under 35 U.S.C. § 103. (G000272). Glaxo did not respond to this rejection and the application was abandoned on November 29, 1989. (G000275).

Before the '442 patent was abandoned, Glaxo filed a continuation application, Serial No. 07/344,620 (the '620 application). (G000112-113). That application was filed on April 28, 1989. *Id.* The '620 application was identical to the original '442 patent application and had the same original 14 claims. (G000117-122). Glaxo did not file a preliminary amendment changing the claims and, therefore, on June 28, 1989, the Examiner again rejected all 14 claims of the '620 application. (G000130). He used the same rejections that were used in the '442 application. (G000131-132). In addition, the Examiner added another rejection. (G000132). That rejection is unrelated to the substance of this summary judgment motion.

On October 30, 1989, Glaxo filed an Amendment to the claims. (G000139-146). Glaxo amended claim 1 to again narrow the claim element "ethanol" to a subset of ethanol, namely "a stabilizing effective amount of." The amended claim is as follows:

> 1. (Amended) A pharmaceutical composition which is an aqueous formulation for oral administration of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation also containing a stabilizing effective amount of ethanol and said composition having a pH in the range of 6.5 to 7.5.

(G000139).

Glaxo also again cancelled claim 4 and essentially made the same arguments that it had made in the '442 patent application. (G000140-145). Unlike in the '442 application, however, Glaxo disclosed an additional reference to the Examiner. (G000144, 146). That reference was UK Patent Application 2,120,938A. *Id.* Glaxo stated that UK Patent Application 2, 120,938A "relates to the combination of anti-ulcer drugs such as ranitidine together with salicylic acid or a salt thereof." (G000144). Glaxo further stated that in the UK application, the excipients "may be formulated in water or organic solvents including a reference to lower aliphatic alcohols, optionally in admixture with water." *Id.* (emphasis added). Glaxo argued, however, that, "there is absolutely no teaching which would lead one of ordinary skill in the art to select ethanol in combination with ranitidine in the expectation of providing an oral formulation which is stabilized in the presence of ethanol." *Id.* (emphasis added). Glaxo therefore argued that its invention was the selection of ethanol over other lower aliphatic alcohols, such as those specifically found in the U.K. application.

By this disclosure, Glaxo acknowledged that ranitidine had been available in the prior art and that it had been in formulations containing lower aliphatic alcohol. **Redacted** is a lower aliphatic alcohol.[16] Glaxo had the opportunity in the face of this prior art to broaden its claims to include **Redacted** in addition to ethanol and to argue to the Examiner that both of these excipients were patentable as stabilizers. It did not do this, however. It only argued that ethanol stabilized the formulation. It argued that its invention was the selection of ethanol over other lower aliphatic alcohols. The Examiner never had a chance to determine whether **Redacted** was patentable as a stabilizing agent for ranitidine. Glaxo told the Patent Office that a

[16] *See* (Exhibit 1 at A005, Dr. Anderson's expert report, March 16, 2006, ¶ 64).

combination of ranitidine and lower aliphatic alcohols, such as Redacted, were known in the prior art, but that the invention selected ethanol over them.

On November 14, 1989, the Examiner rejected all of the then pending claims, claims 1-3 and 5-14. (G000160). Important to this motion, the Examiner maintained the obviousness rejection under 35 U.S.C. § 103. (G000161). The Examiner stated that a new reference, "Chem. Abst. 97-shows ranitidine with an alcohol (2-propanol). *Id.* This art clearly precludes applicant's claims to ranitidine and ETOH."[17] *Id.* The Examiner continued, "97-does show an alcohol and ranitidine in a formulation. *Id.* "As for the allegation of enhanced stability, it has not been demonstrated for the compositions urged as contrasted with any of other pH parameters." *Id.* By this rejection, the Examiner again indicated that the combination of alcohols and ranitidine was in the prior art and that Glaxo had not shown any data establishing enhanced stability resulting from the inclusion of ethanol. *See id.* The Examiner made this rejection final. *Id.*

On March 14, 1990, Glaxo filed a file wrapper continuation application, application Serial No. 07/494,804 (the '804 application). (G000163-166). This is the application that ultimately issued as the '249 patent.

On May 4, 1990, the Examiner again rejected all the claims pending in the application, claims 1-3 and 5-14. (G000169). The Examiner essentially maintained the rejection in the previous application, the '620 patent application.[18] (G000170-171).

On October 31, 1990, Glaxo filed an Amendment. (G000173-178). In the Amendment, Glaxo narrowed claim 1 by inserting "an effective amount" before the term "of ranitidine" and the phrase "also containing" was inserted in place of the phrase "comprising." (G000173). As amended, the claims is as follows:

> 1. A pharmaceutical composition which is an aqueous formulation for an oral administration an effective amount of ranitidine and/or one or more

[17] ETOH is ethanol. *See* Examiner's November 13, 1989 Rejection at p.2 (G000161), which uses "ethanol" and "EtOH" interchangeably.

[18] The Examiner added an additional rejection of double patenting which is not relevant to this summary judgment motion.

> physiologically acceptable salts thereof, said formulation comprising a stabilizing effective amount of ethanol and said composition having a pH in the range of 6.5 to 7.5.

Id.

Glaxo also cancelled claims 8-11 and added new claims 15-17. *Id.* New claims 15-17 all depended on independent claim 1. *Id.* Glaxo argued that the amendments to claim 1 should eliminate the 35 U.S.C. § 112 rejections. (G000174). Glaxo also argued that the claims were not obvious under 35 U.S.C. § 103. (G000175). It argued that the "references do not lead one of ordinary skill in the art in any way to expect that stability of ranitidine in an aqueous oral formulation could be enhanced by the presence of ethanol and does not suggest the presence of ethanol in such compositions." *Id.* (emphasis added). As to the first reference – 97, 61014G – Glaxo said that "there is no teaching whatever that the stability of ranitidine or its salts as an aqueous formulation for oral administration is enhanced by the presence of ethanol and there is no suggestion that ethanol should be included in pharmaceutical formulations containing ranitidine as presently claimed." *Id.* (emphasis added). As to the second reference – Chemical Abstract 104 102280Z--Glaxo wrote that, "[a]gain, there is absolutely no teaching in this reference that would lead one of ordinary skill in the art to expect that ethanol would enhance the stability of ranitidine in aqueous oral formulations or would suggest to one of ordinary skill in the art that ethanol should be added to such formulations." (G000175-176). (emphasis added). Glaxo concluded the Amendment by stating that it was in the process of preparing a Declaration to substantiate the "unexpected effect of ethanol in enhancing the stability of ranitidine in aqueous oral formulations." (G000177). (emphasis added). Glaxo expected to have that Declaration available in about six weeks. *Id.*

On January 22, 1991, the Examiner again rejected all of the pending claims of the application, claims 1-3, 5-7, and 12-17. (G000198). The Examiner stated that the prior rejections in the Office Action of May 4, 1990, had been overcome by the Amendment filed on October 31, 1990. (G00199). The Examiner, however, raised new objections in light of additional documents

that had been filed by Glaxo on January 10, 1991. *Id.* In the new rejections, the Examiner said that the claims were obvious under 35 U.S.C. § 103. (G000199-200). The Examiner argued that the invention was obvious in light of Padfield (GB 2142820)("Padfield"). *Id.* Padfield was owned by Glaxo. (Exhibit 11, '820 patent, cover). The Examiner noted that in Padfield, Glaxo already had been awarded a patent for ranitidine formulations having enhanced stability at a pH of 6.5 to 7.5. (G000200).

The Examiner asked Glaxo to demonstrate, through experimental data, that its purported invention produced "unexpected results," showing "a definite improvement over" Glaxo's prior patent, Padfield. *Id.* The Examiner wrote that because Glaxo's prior patent (Padfield) taught "an aqueous composition of ranitidine, it is considered well within the state of the art to choose ethanol as an additive which would be considered pharmaceutically acceptable when formulating this composition." *Id.* (emphasis added).

The Examiner again asked for evidence from Glaxo that its choice of ethanol was not merely a "choice among known conventional excipients," as Glaxo had still, four years after filing its first application, not substantiated its claim that ethanol (above other available excipients) produced "any unexpected results." *Id.*

On May 10, 1991, Glaxo requested reconsideration of the January 22, 1991, rejection and argued that its prior patent (Padfield) did not teach an enhancement of ranitidine formulations using ethanol. (G000204-207). In support of its claim to the unique and specific benefits of ethanol to stabilize ranitidine, Glaxo submitted the Declaration of one of its scientists, Dr. Hempenstall. (G000208-211). Dr. Hempenstall's declaration provided experimental data that the Patent Office had demanded since its first rejection. *Id.* Dr. Hempenstall, who at the time was "a Research Leader" in the Pharmacy Division of Glaxo, declared that ethanol added to Glaxo's

ranitidine formulation, resulted in a "surprising enhancement in the stability of the ranitidine . . .." (G000209).[19]

The experimental data submitted by Dr. Hempenstall demonstrated enhanced stability by alleging an increase in the shelf life of the various formulations with ethanol as compared to the same formulations without ethanol. (G000211). Dr. Hempenstall concluded that his data showed that "a significant and surprising enhancement in the stability of the ranitidine is achieved by the addition of ethanol." (G000209). (emphasis added).

Using Dr. Hempenstall's Declaration, Glaxo argued extensively to the Patent Office that the use of ethanol as a stabilizing agent for ranitidine was not obvious. (G000204-207). The sheer volume of references to ethanol (and nothing else) as the stabilizer in this invention is highlighted by the final argument that Glaxo made to the Examiner which convinced the Examiner to allow the patent:

> The Official Action bases the rejection of the present application under 35 U.S.C. § 103 on a statement that the use of ethanol is considered merely to be a choice among known conventional excipients. Applicant acknowledges that ethanol has previously been used in pharmaceutical compositions. However, the purpose for which ethanol has been included has been either as a solvent or as a preservative against bacterial contamination. There was, however, no reason to suppose that either of these functions of ethanol would have had any beneficial effects in terms of limiting the degradation of ranitidine in aqueous formulations thereof.
>
> For this reason, there would have been no motivation whatever for one of ordinary skill in the art to include ethanol in an aqueous ranitidine formulation. Ranitidine is very soluble in water and ethanol is quite unnecessary to assist in

[19] Glaxo's uncorroborated data, essential to the issuance of the '249 patent, was proven to be of dubious origin in the *Pharmadyne* case. *Pharmadyne*, 32 F. Supp. 2d at 313. Dr. Hempenstall only disclosed a subset of the data supporting the experiments Glaxo had performed, apparently to enhance the appearance of an increase in stability. *Id.* This led the *Pharmadyne* court to conclude that there was the appearance of improper behavior by Glaxo in prosecuting the patent" and that it was "great." *Pharmadyne* at 312. The *Pharmadyne* court, however, found that Dr. Hempenstall's failure to provide the Patent Office with a complete disclosure of the experimental data did not amount to an intentional, knowing fraud on the Patent Office. *Pharmadyne* at 313. In this litigation, Teva has learned that another Glaxo scientist, Mrs. Bird, analyzed Glaxo's stability data and concluded that "the presence of ethanol appears to produce a slight improvement in stability." (Exhibit 12 at A054) (emphasis added). "I think it is debatable whether or not you pursue this patent claim. The analysts can see no chemical reason why ethanol should enhance stability. *Id.* Dr. Hempenstall was copied on this memo, yet he told the Patent Office that his analysis of the data (found to be incomplete by the *Pharmadyne* Court) showed that the ranitidine stability was "a highly significant and valuable improvement." (G000211).

> the dissolution of ranitidine in the formulation. In addition, other and better preservatives are available.
>
> Furthermore, there is a clear disincentive against the use of ethanol in aqueous formulations. Thus, an important use of ranitidine is in the treatment of peptic ulcers and related conditions, and it is well known that alcohol (i.e. ethanol) can aggravate such conditions. In fact, the amount of ethanol required for use according to the present invention is at such a low level that no adverse effects are observed as a result of the presence of ethanol, but fairly clear and beneficial effects on drug stability are evident.
>
> However, the fact that ethanol has a known effect in aggravating one of the main conditions that the compositions according to the invention are intended to treat would be a clear disincentive to including ethanol without knowledge of the beneficial effects on stability. This knowledge is, of course, provided only by the present invention. Thus, there was no motivation whatever for one of ordinary skill in the art to include ethanol in aqueous ranitidine formulations and the beneficial effects obtained by the use of ethanol were most definitely unexpected.

(G000205-206)(emphasis added).

The Examiner allowed Glaxo's claims on June 3, 1991. (G000212).

H. Literal Infringement

Teva's proposed ranitidine formula contains water and **Redacted**

(Exhibit 7 at A028-A029). This is in contrast to the '249 patent having a preferred 7.5% w/v of ethanol. (Col. 2, line 59). Glaxo, in response to a request to admit, has conceded that Teva's formulation does not literally infringe the '249 patent.[20] Because the doctrine of equivalents is not available to expand the claim element "ethanol" as a matter of law, dismissal of Glaxo's infringement claims is appropriate.

IV. ARGUMENT

A. The Law Regarding Summary Judgment

The standard for summary judgment in a patent case is no different from any other type of case. *Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1571 (Fed. Cir. 1984). "Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *United States Gypsum Co.*

[20] *See* (Exhibit 6 at A019) (Glaxo Response to Request for Admission No. 87).

v. Nat'l Gypsum Co., 74 F.3d 1209, 1212 (Fed. Cir. 1996). Here, this Court should rule as a matter of law that Teva's formulation does not infringe the '249 patent because the doctrine of equivalents is not available to expand the scope of the claim limitation "ethanol" as a matter of law.

B. The Law Of Patent Infringement

The first step of any infringement analysis involves determining the scope and meaning of the asserted claims. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998)(*en banc*). The Federal Circuit patent law is now clear that the intrinsic record (the patent claims, the patent specification and the patent prosecution history) is the primary source of evidence to properly construe the meaning of a patent claim. *See Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005)(*en banc*).

Here, the parties disagree as to the meaning of the term "ethanol," but under either definition Teva is entitled to summary judgment of non-infringement. No matter what the definition of "ethanol" is, it cannot be expanded to cover **Redacted** as a matter of law. Legal limitations on the application of the doctrine of equivalents are questions of law, appropriate for summary determination. W*arner-Jenkinson*, 520 U.S. at 39, n.8 ("As stated by the *Warner-Jenkinson* Court, the various legal limitations on the application of the doctrine of equivalents are to be determined by the court."). *Id.*

C. Teva's Formulation Does Not Infringe The Claims Of The '249 Patent Under The Doctrine Of Equivalents

Glaxo must resort to the application of the doctrine of equivalents to capture the use of **Redacted** as an infringing equivalent of its invention. The doctrine of equivalents, however, is not available to Glaxo here.

A core tenet of patent law is that a patentee must "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 ¶ 2. Inventors are required to describe their work in "full, clear, concise, and exact terms," to foster a

balance encouraged by the law between "inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new designs beyond the inventor's exclusive rights." *Festo Corp. v. Shoketsu Kinzoku*, 535 U.S. 722, 731 (2002).

Indeed, the purpose of a patent claim is to provide notice to competitors regarding the scope of the patent grant. *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 232 (1942)("The inventor must inform the public . . . of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not")(internal quotes omitted). A full and complete disclosure of the invention allows competitors to understand the bounds of the invention and encourages innovation by challenging those competitors to explore and create non-infringing uses of the claimed invention. *See Festo*, 535 U.S. at 731.

The Supreme Court has long recognized that the "carefully crafted bargain" at the heart of the United States patent system "depends almost entirely upon a backdrop of free competition in the exploitation of unpatented designs and innovations." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989). Here, Glaxo has disclosed and claimed precisely what it regarded as its invention – the use of ethanol to enhance ranitidine stability. Glaxo's narrow prosecution of those claims gave notice to its competitors that its patent covered the use of ethanol to enhance the stability of ranitidine syrup formulations, and nothing more.

The doctrine of equivalents inherently conflicts with the well-founded notice objectives of patent law. At least five important legal bars that spring from the notice function of patents prevent Glaxo from broadening the '249 patent under the doctrine of equivalents. First, prosecution history estoppel bars a patentee from expanding his claims to embrace subject matter surrendered by argument to the Patent Office. *Pharmacia & Upjohn Co. v. Mylan Pharms., Inc.* 170 F.3d 1373, 1377 (Fed. Cir. 1999). Second, prosecution history estoppel bars a patentee from expanding his claims to embrace subject matter surrendered by amendment during the

prosecution of the patent. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002). Third, the patentee cannot use the doctrine of equivalents to vitiate claim limitations. *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed. Cir. 1998). Fourth, a patentee may waive or dedicate to the public aspects of the invention that might have been claimed. *Johnson & Johnston Assocs. Inc. v. R.E. Service Co.*, 285 F.3d 1046 (Fed. Cir. 2002). The facts in this case are analogous to this line of cases. Fifth, *Wilson Sporting Goods* prevents a patentee from expanding claims under the doctrine of equivalents to such a degree that the hypothetical claim covering the equivalent would be invalid. *See Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 683 (Fed Cir. 1990).

Each of these five bars prevents the use of the doctrine of equivalents by Glaxo to claim infringement by Teva's formulation. Each legal bar, although focused on different aspects of the patenting process, furthers a common underlying tenant of patent law – that the Patent Office should be the first arbiter of what is patentable. *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420, 1424 (Fed. Cir. 1997). If a patentee does not subject the full, known scope of his invention to the Patent Office for its scrutiny, the patentee later will be barred from broadening his claims under the doctrine of equivalents. There is no dispute here that Glaxo claimed a narrow improvement over its own prior patent (Exhibit 11) and over patents by others which used lower aliphatic alcohols in conjunction with ranitidine. The field was so crowded that Glaxo was forced to argue that ethanol alone imparted increased stability to its formulations. Even then, it was forced to provide data as proof. Glaxo did not argue that **Redacted** was patentable as a stabilizer for ranitidine even though Dr. Long had thought of that idea before the patent application was filed. By disclosing, claiming and arguing only ethanol, Glaxo advised the public that its invention was only a very narrow slice of the field of art – that narrow slice was ethanol as a stabilizer.

When inventors claim narrowly, courts also apply the doctrine of equivalents narrowly, if at all. *Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420, 1424 (Fed. Cir.

1997)(affirming summary judgment of non-infringement and noting the case to be an example of "why the law restricts application of the doctrine of equivalents without further fact finding" in some cases.). The Federal Circuit has been clear that a contrary rule would cause claim language to be "reduced to functional abstracts, devoid of meaningful structural limitations on which the public could rely." 126 F.3d at 1424. This tenant is fully realized only when an applicant precisely and fully discloses the full extent of his invention to the Patent Office, so that competitors can rely on the scope of the disclosed, claimed and examined invention in order to avoid infringement. Here, Glaxo disclosed, claimed, argued and ultimately persuaded the Patent Office that its invention was ethanol as a stabilizing agent in its ranitidine oral solution. Glaxo is entitled to no more scope of patent protection than that.

1. Glaxo Is Estopped From Broadening The Term "Ethanol" Beyond Just Ethanol Because It Surrendered By Argument Any Broader Subject Matter

Arguments and representations made to the Patent Office by Glaxo limit the scope of available equivalents. *See Tanabe Seiyaku Co. Ltd v. ITC*, 109 F.3d 726, 733 (Fed. Cir. 1997). To overcome the Examiner's obviousness rejections, Glaxo argued that "only by the present invention," would one of ordinary skill in the art recognize the stabilizing benefits of ethanol in the formulation. (G000206)(emphasis added). These arguments responded to the Examiner's assertion that the selection of ethanol among other "known conventional excipients" was merely a matter of design choice. (G000200). By this argument, Glaxo surrendered any claim to other "known conventional excipients," such as **Redacted** for use as a stabilizing agent in its ranitidine formulation. (G000204-211). Glaxo also argued that its invention was the selection of ethanol over other lower aliphatic alcohols.

The facts in *Tanabe* are surprisingly similar to the facts in this case. Tanabe owned a patent for preparing the pharmaceutical product, diltiazem hydrochloride. The claimed process included an "N-alkylation" chemical reaction using a starting material referred to as "TZP" in an acetone solvent. The accused process used an "N-alkylation" chemical reaction and "TZP" as a

starting material. The accused process, however, used butanone as the solvent. *See Tanabe*, 109 F.3d at 729. Butanone and acetone are similar; they both are "ketones" (organic compounds having a "carbonyl group"). *Id.* Moreover, they are "homologs," that is, they differ only in that butanone contains an additional "methylene group." *Id.* There was evidence in *Tanabe*, as there is here, that the inventor had experimented with a number of solvents before filing its patent application, but disclosed to the Patent Office and claimed only one type of solvent. 109 F.3d at 732.

During prosecution of the patent application, Tanabe overcame obviousness rejections by arguing that its process using acetone "gave unexpectedly better results than other combinations of bases and solvents." *Id.* at 733. The *Tanabe* court, therefore, limited the doctrine of equivalents to the deliberately narrowed claim at issue, so as not to undermine the notice function the public is entitled to rely on to avoid infringement. *See id.* The *Tanabe* court drew upon Federal Circuit precedent to note that:

> the doctrine of equivalents is not available for the attainment in court of a scope of protection which encompasses subject matter deliberately removed from examination by the PTO during prosecution through narrow claiming. . . . It is impermissible to erase under the doctrine of equivalents "meaningful limitations of the claim on which the public is entitled to rely in avoiding infringement."

Tanabe, 109 F.3d at 732 (quoting *Genentech, Inc. v. Wellcome Found., Ltd.*, 29 F.3d 1555, 1568 n.41 (Fed. Cir. 1994)).

In this case – as in *Tanabe* – the patented and accused compounds belong to the same class of chemicals (i.e. they both are alcohols), but are nonetheless different chemicals. *See Glaxo v. Pharmadyne* at 267. The difference between the acetone and butanone in *Tanabe* is analogous to the difference between ethanol and **Redacted** in this case.

As in *Tanabe*, Glaxo experimented with both ethanol and **Redacted** In this case, **Redacted** failed for reasons unrelated to the stability of ranitidine, i.e., a lack of

antimicrobial (preservative) properties.[21] As in *Tanabe*, Glaxo limited its disclosure in the specification and its claims to one specific compound – ethanol. Finally, as in *Tanabe*, Glaxo obtained its patent by presenting experimental data to show "surprising results" stemming from the use of ethanol alone. Just as the inventor in *Tanabe* was precluded from utilizing the doctrine of equivalents to undo its narrow claim scope to capture subject matter it deliberately did not present for the Patent Office's review, so should Glaxo be precluded from capturing the use of Redacted within the scope of its issued claims through the doctrine of equivalents.

In the concurring opinion in *Johnson & Johnston Assocs. Inc. v. R.E. Service Co.*, 285 F.3d 1046 (Fed. Cir. 2002), Judge Rader suggested a unified theory of infringement under the doctrine of equivalents that is useful here. Judge Rader's opinion advocates that infringement by equivalents should be predicated on a showing by the patentee that the alleged equivalent was not foreseeable at the time of drafting. *Johnson*, 285 F.3d at 1057. Judge Rader's well-reasoned opinion is that "[w]hen one of ordinary skill in the relevant art would foresee coverage of an invention, a patent drafter has an obligation to claim those foreseeable limits." *Johnson & Johnston Assocs., Inc. v. R.E. Service Co.*, 285 F.3d at 1057 (Rader, J. concurring). "In other words, the patentee has an obligation to draft claims that capture all reasonably foreseeable ways to practice the invention. The doctrine of equivalents should not rescue a claim drafter who does not meet this obligation and provide such notice." *Id.* Dr. Long foresaw the use of Redacted as a stabilizer but did not disclose it in the patent or claim it. Judge Rader's analysis would limit Glaxo's claims to just ethanol.

In *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373 (Fed. Cir. 1999), the patentee asserted a claim of patent infringement against Mylan for infringement of a

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[21] As will be discussed later, the ethanol in the invention has Redacted (Exhibit 1 at A002, Anderson Rpt., March 16, 2006, ¶ 40). Dr. Long found that Redacted did not have appropriate antimicrobial properties and, therefore, did not pursue it in his formulation. (Exhibit 9 at A042-A043). He did foresee, however, that it would perform the stabilizing function. (Exhibit 10 at A045).

pharmaceutical composition that included "spray-dried lactose as the principle excipient." *Pharmacia* at 1374. Mylan's formulation contained anhydrous lactose as the principle excipient, but not spray-dried lactose. Because Mylan's formulation did not contain spray-dried lactose, the patentee's infringement claim (like Glaxo's here) relied on the doctrine of equivalents. *Id.* at 1375.

In analyzing whether the doctrine of equivalents applied to Mylan's formulation, the Federal Circuit analyzed the prosecution history of the patent and noted that Upjohn had emphasized the necessity of using spray-dried lactose to distinguish its formulation over the prior art. *See id.* at 1377. In support of the policy underlying the public notice function of patents, the Federal Circuit found that "an Upjohn competitor would reasonably interpret [these] statements to mean that spray-dried lactose was an indispensable component of the claim formulations." *Id.* at 1378.

As in *Pharmacia*, Glaxo emphasized by argument that "only by the present invention" (which was described as ethanol) are the advantages available:

> . . . the fact that ethanol has a known effect in aggravating one of the main conditions that the compositions according to the invention are intended to treat would be a clear disincentive to including ethanol without knowledge of the beneficial effects on stability. This knowledge is, of course, provided **only by** the present invention.

(G000206)(emphasis added). It also argued that its invention was the selection of ethanol over other lower aliphatic alcohols in the prior art.

These statements serve to notify the public and a competitor like Teva that ethanol was the singularly "important" component of the pharmaceutical composition that improved the stability of ranitidine. *Pharmacia* at 1378 ("An Upjohn competitor would reasonably interpret [the inventor's declaration] statements to mean that spray-dried lactose was an indispensable component of the claimed formulations.").

The conclusion that ethanol was "indispensable" to Glaxo's formulation is further bolstered by the evidence. Glaxo tested **Redacted** as a preservative before it filed for is

patent and determined that it would not work. (Exhibit 9 at A042-A043). Nonetheless, Dr. Long foresaw that Redacted could function as a stabilizer for ranitidine, but he abandoned it because it did not perform the other functions that ethanol performed, such as the preservative (antimicrobial) function. (Exhibit 10 at A045). This evidence underscores the claim scope that Glaxo intended for the '249 patent, and it reinforces the correctness of the public's right to rely on the disclosure in the '249 patent, a disclosure which clearly lays claim to ethanol alone as the critical feature of the invention.

Glaxo surrendered Redacted as an equivalent by virtue of its narrow disclosure in the patent and the narrow arguments it made to the Patent Office to obtain allowance of the '249 patent. In fact, Glaxo surrendered all "known conventional excipients" other than ethanol by submitting the Hempenstall declaration to rebut the Patent Office's arguments that ethanol was merely an obvious design choice among "known conventional excipients. (G000204-211). Even though the Patent Office argued that ethanol was just a design choice among known conventional excipients, Dr. Hempenstall argued that ethanol led to the surprising stabilization of ranitidine. (G000211, ¶7). Dr. Hempenstall did not argue that any other known conventional excipients also stabilized ranitidine, which was the substance of the Examiner's rejection. Moreover, Glaxo argued that its invention was the selection of ethanol over other lower aliphatic alcohols in the prior art. Glaxo should now be barred from asserting that Redacted is also within the scope of its invention, contrary to the central and only arguments it made to the Patent Office to obtain its patent.

2. Glaxo Is Estopped From Broadening The Term "Ethanol" Beyond Just Ethanol Because It Made Narrowing Amendments To The Claims During The Prosecution Of The '249 Patent

The Supreme Court has firmly established that a patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of subject matter broader than the amended claim. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 741 (2002). In this case, the Patent Office rejected Glaxo's original claim 1 because of the indefinite

nature of the claim (§ 112) and due to the Patent Office's conclusion that the claim was obvious in light the prior art (§ 103). In response to these rejections, Glaxo made a narrowing amendment to claim 1. Glaxo added "stabilizing effective amount of" to the "ethanol" element of claim 1 to define the amount of ethanol present. (G000139).

An amendment to overcome a § 112 or a §103 rejection is unquestionably related to patentability, invoking a presumption of surrender. *See Festo*, 535 U.S. at 741; *SmithKline Beecham Corp. v. Excel Pharms., Inc.*, 356 F.3d 1357, 1361 (Fed. Cir. 2004).

The amendment to claim 1 was made to overcome the Examiner's first rejection under § 112 and to emphasize that, unlike prior art ranitidine formulations with ethanol or other "lower aliphatic alcohols," the invention involved a "stabilizing" amount of ethanol alone. (G000207, G000139-140). At the time that it narrowed claim 1, Glaxo also disclosed a prior art reference which showed ranitidine "formulated in water or organic solvents including . . . lower aliphatic alcohols."[22] (G000144).

Glaxo surrendered its original claim to ranitidine formulations with ethanol and instead claimed only ranitidine formulations with a "stabilizing" amount of ethanol. Glaxo made this amendment at the same time it disclosed a prior art reference that had disclosed ranitidine solutions with "lower aliphatic alcohols," such as **Redacted** In response to the Examiner's rejections and the prior art it identified, Glaxo could have broadened its claim by changing "ethanol" to "lower aliphatic alcohol" or it could have broadened its claim by changing "ethanol" to a "stabilizing effective amount of a lower aliphatic alcohol," or even to **Redacted**

Similarly, it could have kept "ethanol" as "ethanol" and argued that the Examiner was wrong. Instead, it narrowed its claim from "ethanol" to "stabilizing effective amount of ethanol" thus giving up claim scope broader than the amended language, such as "a lower aliphatic

[22] **Redacted** is a lower aliphatic alcohol. (Exhibit 1 at A005, Anderson Report., March 16, 2006, ¶64).

alcohol." The law, therefore, presumes that Glaxo, by its amendment, surrendered all ranitidine formulations broader than those with a "stabilizing effective amount" of "ethanol."

To rebut this presumption under *Festo*, Glaxo must prove that Redacted as a stabilizing agent was objectively unforeseeable at the time the amendments were made.[23] *Festo* at 741. Other courts interpreting *Festo* also have concluded that *Festo's* surrender analysis is best applied under a rubric of foreseeability. Indeed, *Festo* held that to rebut a presumption of surrender, "a patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 287 F. Supp. 2d 126, 137 (D. Mass. 2003)(quoting *Festo*, 535 U.S. at 741).

The undisputed record here, however, establishes as a matter of law that the use of Redacted to stabilize ranitidine syrup was not only objectively foreseeable, but was *actually* foreseen by Dr. Long. Indeed, Dr. Long wrote in his notebook that both ethanol and Redacted would stabilize ranitidine. (Exhibit 10 at A045). Knowing that Redacted was suitable as a stabilizer in its ranitidine formulation, Glaxo cannot now claim that such a use was not foreseeable when it drafted its original narrow patent claims and then further narrowed them during prosecution. Glaxo, therefore, cannot rebut the *Festo* presumption that it surrendered Redacted as an equivalent to ethanol in its patent. *See Festo* at 740-741. Prosecution history estoppel, therefore, bars Glaxo from relying on the doctrine of equivalents to assert infringement of Redacted in a ranitidine oral solution.

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[23] Under *Festo*, Glaxo may rebut the presumption of surrender by showing that "the equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question." *Id.* at 740-741. Glaxo cannot rebut the *Festo* presumption under any circumstance given the facts before this Court.

3. Glaxo Is Estopped From Broadening The Term "Ethanol" To Mean Redacted Because That Interpretation Would Vitiate The Claim Element "Ethanol"

The "all elements rule" of patent infringement analysis holds that an accused product or process cannot infringe unless it contains each and every limitation of the claim, either literally or by an equivalent. *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed. Cir. 1998)("If a theory of equivalents would vitiate a claim limitation, however, then there can be no infringement under the doctrine of equivalents as a matter of law."); *Kustom Signals, Inc. v. Applied Concepts, Inc.*, 264 F.3d 1326, 1333 (Fed. Cir. 2001). This principle has two primary implications for the doctrine of equivalents. First, the "all elements rule" requires that equivalence be assessed on an element-by-element basis, as opposed to an invention-as-a-whole analysis. *See Warner-Jenkinson*, 520 U.S. at 29; *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 935 (Fed. Cir. 1987)(*en banc*). Second, an element of an accused product is not, as a matter of law, equivalent to an element of the claimed invention if the substitution would entirely vitiate the claim element, *Warner-Jenkinson*, 520 U.S. at 29.

These guiding principles were recently restated and applied by the Federal Circuit in *Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350 (Fed. Cir. 2005). In that case, Freedman and American both made stowable seats used in public transportation. *Id.* at 1357. The issue was whether Freedman's patented seat support that was "slidably mounted" was equivalent to American's seat support that was "rotatably mounted." *Id.* at 1354-55. The district court found that they were equivalent. The Federal Circuit reversed and held that the district court's finding of infringement under the doctrine of equivalents entirely vitiated the "slidably mounted" limitation of the patent. *Id.* at 1362.

The Federal Circuit found that the subject matter claimed in the patent involved relatively simple and well-known technologies. *See id.* The inventors were aware of other types of seat mountings. *Id.* Yet, the inventors specifically limited their claims to a "slidably mounted" seat. *Id.* Members of the public were, therefore, justified in relying on this specific language in

assessing the bounds of the claim. *See id.* Accordingly, the Federal Circuit reasoned that construing the patent claims to include other mounting mechanisms under the doctrine of equivalents would unjustly undermine the reasonable expectations of the public. *Id.* (citing *Sage Prods. Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1425 (Fed. Cir. 1997)(A skilled patent drafter would foresee the limiting potential of the "over the slot" [slidably mounted] limitation, and Devon's foreseeable alteration of the claimed structure bars application of the doctrine of equivalents.).

In this case, Dr. Long foresaw that both ethanol and **Redacted** would stabilize ranitidine. As in *Freedman*, one of ordinary skill in the art would be justified in relying on Glaxo's specific and narrow specification and claim. Any claim that would cover **Redacted** would entirely vitiate the claim element "ethanol" and also vitiate the public's expectation regarding the narrowness of this element.

Glaxo's endorsement of ethanol (and only ethanol) to obtain its patent limits the scope of its claim to ethanol alone. The doctrine of equivalents is therefore not available to Glaxo to claim **Redacted** in the present action, as it would vitiate the very limitation that Glaxo insisted imparted novelty to its invention – the use of ethanol over all other "known conventional excipients" and over other "lower aliphatic alcohols."

4. Glaxo Is Estopped From Broadening The Term "Ethanol" To Mean Redacted Because Redacted Was Waived Or Dedicated To The Public

The Federal Circuit has a line of cases dealing with dedicating portions of an invention to the public or waiving portions of an invention. Under this line of cases, a patentee might disclose more than one embodiment of his invention in the specification but for some reason only claim one of those many embodiments. In those situations, the Federal Circuit has held that the embodiments that were disclosed but not claimed are waived or dedicated to the public. The subject matter that was waived or dedicated to the public, therefore, is not available to the patentee to broaden the scope of his claims under the doctrine of equivalents. *Maxwell v. J.*

Baker, Inc., 86 F.3d 1098 (Fed. Cir. 1996); *Johnson & Johnston Assocs. Inc. v. R.E. Service Co.*, 285 F.3d 1046 (Fed. Cir. 2002).

Although the facts in this case are not directly the same as the facts in the traditional waiver or dedication to the public cases, the facts in this case are closely analogous and the policy behind the waiver/dedication to the public doctrine should apply here. As mentioned throughout this brief, all of the doctrines that are discussed in this brief rely heavily on the strong undercurrent in the patent law that the Patent Office should be the first arbiter of what is patentable. An inventor is obligated to present the full range of his invention to the Patent Office for its scrutiny. If the inventor holds back in any respect, or retreats from the original breadth of his claimed invention, then the consequences to the inventor are a severe narrowing of the claim that issues from the Patent Office. Because of this doctrine, the concept of foreseeability is used to determine whether or not a patentee has met his obligation of disclosing the full scope of his invention. When a patentee fails to disclose all foreseeable aspects of his invention, the law, through various policies and doctrines, limits the inventor from later reclaiming in court what he initially did not claim in the Patent Office.

In this case, Dr. Long did foresee that both **Redacted** and ethanol could have stabilizing effects on ranitidine oral solutions. His notebook is clear and unequivocal on that point. Nonetheless, when Dr. Long filed his patent application, he did not disclose and claim both **Redacted** and ethanol. Instead, he disclosed and claimed only ethanol. Just as in the waiver and dedication to the public cases, Dr. Long was aware of other foreseeable aspects of his invention, but limited his claims to just a subset of them. It should make no difference that Dr. Long failed to put his other embodiment, **Redacted**, in the patent specification; he knew it and he should not be able to escape waiver and dedication to the public merely by failing to disclose the full potential scope of his invention to the public in his specification.

Indeed, of the two situations, 1) the disclosure of <u>all</u> foreseeable embodiments in the specification and the claiming of less or 2) the disclosure of only one of many foreseeable

embodiments in the specification and the claiming of that sole embodiment, the latter situation should be even less favored from a public policy standpoint. *See Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries, Inc.*, 145 F.3d 1303, 1311 (Fed. Cir. 1998) explaining the doctrine of equivalents in the context of a means-plus-function limitation and noting "there is no policy-based reason why a patentee should get two bites at the apple. If he or she could have included in the patent what is now alleged to be equivalent, and did not, leading to a conclusion that an accused device lacks an equivalent to the disclosed structure, why should the issue of equivalents have to be litigated a second time?") At least in the former situation, the public gains the benefit of the inventor's knowledge about other foreseeable embodiments because they are disclosed to the public in the specification. When an inventor does not even disclose the other foreseeable aspects of his invention, the public loses the benefit of that knowledge and the bargain struck between the public and patentee through the grant of a patent is shortchanged. Thus, although the facts in this case are not directly the same as the facts in waiver or dedication to the public cases, the facts in this case are more severely detrimental to the public and the bargain it struck with Glaxo, and the waiver or dedication to the public of claim scope is even more imperative. Glaxo should have its claim scope limited under the doctrine of waiver/dedication to the public.

5. Glaxo Is Estopped From Broadening The Term "Ethanol" To Mean Redacted Because Such A Hypothetical Claim Would Be Invalid

Glaxo also is prohibited from using the doctrine of equivalents to capture Redacted because a claim to Redacted to stabilize ranitidine would not have been patentable. The Federal Circuit has been clear in holding that "a patentee should not be able to obtain, under the doctrine of equivalents, coverage which he could not lawfully have obtained from the PTO by literal claims." *Wilson Sporting Goods v. David Geoffrey & Assoc.*, 904 F.2d 677, 684 (Fed. Cir. 1990). The *Wilson Sporting Goods* court set forth the "hypothetical claim" analysis, an objective method available to a court to determine whether the doctrine of equivalents is appropriate. 904

F.2d at 684. Under this analysis, a court is directed to visualize "a hypothetical patent claim, sufficient in scope to literally cover the accused product," and then determine whether "that hypothetical claim could have been allowed by the PTO over the prior art." *Id.*

The Federal Circuit in *Wilson Sporting Goods* emphasized that the doctrine of equivalents "exists to prevent a fraud on the patent, *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.* 339 U.S. 605, 608, 94 L. Ed. 1097, 70 S. Ct. 854 (1950), *not* to give a patentee something which he could not lawful have obtained from the PTO had he tried." *Wilson*, 904 F.2d at 684. Moreover, the *Wilson Sporting Goods* analysis is nothing more than a restatement of the well known patent maxim that a claim should be interpreted to preserve its validity, if possible. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d at 749.

The hypothetical claim presented by Glaxo's assertion of infringement under the doctrine of equivalents would be one that includes **Redacted** as the stabilizing component of an aqueous ranitidine formulation. This hypothetical claim would not be patentable, however. It would be invalid under 35 U.S.C § 112. To understand this analysis, it is necessary to discuss a few more "facts" in the case. Glaxo has hired a technical expert to give his "opinion" that the use of **Redacted** would not have been foreseeable at the time that Glaxo's patent application was filed. Indeed, his "opinion" is that one skilled in the art would not have foreseen the use of **Redacted** as a stabilizer at that time.[24] The law is clear that an expert cannot create an issue of fact through unsupported and conclusory opinions. *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1050-51 (Fed. Cir. 2001) (refusing to consider conclusory opinions set forth in an expert's affidavit because no factual evidence was provided in support thereof) (applying Third Circuit regional law); *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed. Cir. 1999) (ruling that an "expert['s] testimony

[24] Glaxo's expert provides no facts to back up his opinion and does not explain his opinion in view of Dr. Long's notebook. (Exhibit 13 at A064, Anderson Rebuttal, April 24, 2006, ¶ 34; Exhibit 10 at A045). Moreover, Dr. Anderson's opinion is just that, an opinion. It can not contradict the facts in this case to thwart summary judgment.

contradicting the plain language of [an anticipatory] reference [did] not create a genuine issue of fact").

Dr. Anderson's opinion flatly contradicts the "fact" in this case that Dr. Long actually did foresee the use of Redacted as a stabilizer for ranitidine. Teva, therefore, believes that there are uncontroverted "facts" supporting the proposition that the use of Redacted was, indeed, foreseeable. If, however, this Court feels that Dr. Anderson's "opinion" contradicts Dr. Long's notebook entry and creates a fact issue, then Teva believes that the *Wilson Sporting Good* analysis would render a claim encompassing Redacted invalid under 35 U.S.C. § 112. Thus, whether Redacted was foreseeable or whether it was not foreseeable, Teva's Redacted formulation can not infringe as matter of law. After all, the Redacted can only be foreseeable or not foreseeable. There are no other possibilities. Under each scenario, however, Glaxo is legally barred from broadening its claims.

Assuming that Dr. Anderson's opinion is given weight, his opinion establishes that at the time Glaxo filed its patent application, Redacted would not have been foreseeable as a stabilizer for ranitidine. Because the patent specification as filed does not disclose Redacted and does not give any indication that Redacted or any other known conventional excipient or any other lower aliphatic alcohol could be used as a stabilizer, there is no way that one skilled in the art would have understood the invention to be as broad as the use of Redacted to stabilize ranitidine. It was not foreseeable. When a patent specification is so narrow that it does not support broader claims, the claims are invalid under 35 U.S.C. § 112. *North American Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1577 (Fed. Cir. 1993), *cert. denied*, 511 U.S. 1069 (1994)("A patent applicant cannot disclose and claim an invention narrowly and then, in the course of an infringement suit, argue effectively that the claims should be construed to cover that which is neither described nor enabled in the patent.").

In determining whether broad claims can be supported by a narrow specification, the Patent Office uses a foreseeability analysis. This analysis has been also used by the Federal Circuit. *See Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 954 (1987)("If an invention pertains to an art where the results are predictable, e.g., mechanical as opposed to chemical arts, a broad claim can be enabled by disclosure of a single embodiment."). In art fields that are unpredictable, i.e., where an extension of the invention beyond what is disclosed in the specification is unforeseeable, the Patent Office and the Federal Circuit limit the scope of allowable claims to only those aspects of the invention that are disclosed in the specification. *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970)("In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."); *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005)("It is well recognized that in the "unpredictable" fields of science, it is appropriate to recognize the variability in the science in determining the scope of the coverage to which the inventor is entitled. Such a decision usually focuses on the exemplification in the specification."). When the art field is predictable, then a narrow specification may support broader claims because those broader claims would be foreseeable. In this case, (and assuming Dr. Anderson's opinion is correct) the narrow disclosure in Glaxo's '249 patent specification could not have supported a broader claim to **Redacted** because, as Dr. Anderson admits, the **Redacted** stabilizer would not have been foreseeable. Had Glaxo presented a claim broad enough to cover **Redacted**, the Patent Office would have rejected the claim under § 112.

Because a claim should be interpreted to preserve its validity if possible, the hypothetical claim covering **Redacted** should not be adopted because such a claim would be invalid under § 112. Under *Wilson Sporting Goods*, the claims cannot be broadened to cover **Redacted** given the narrow disclosure in the specification.

D. Even If Glaxo's Claim Can Legally Be Broadened To Include Redacted Teva Does Not Infringe The Claim Because Glaxo Has Failed To Meet Its Burden Of Proof

In determining whether an element of a claim is equivalent for purposes of the doctrine of equivalents, the traditional test is the one cited by the Supreme Court in *Graver Tank*. 339 U.S. at 608. Under this test, the alleged equivalent element must perform substantially the same function in substantially the same way to achieve substantially the same result. *Id.* In this case, Glaxo's own expert opined that the ethanol in Glaxo's ranitidine oral solution performs

Redacted

(Exhibit 1 at A002, Anderson Report, March 16, 2006, ¶ 40). Dr. Anderson's opinion is supported by the prosecution history in which Glaxo admitted that the traditional uses of ethanol were as a solvent and an antimicrobial agent. (G000205). Dr. Anderson's opinion also is supported by Dr. Long's experiments. Dr. Long abandoned **Redacted** because it did not perform the antimicrobial (preservative) function. (Exhibit 8 at A039-A041, Long. Tr. at 408-09; 445, lines 1-8); *Pharmadyne* at 278.

In order for Glaxo to prove that **Redacted** is the equivalent of ethanol, it must prove that **Redacted** performs the same functions as ethanol. During his deposition, Dr. Anderson admitted that he had no evidence that **Redacted** acted as an antimicrobial agent in Teva's formulation. (Exhibit 14 at A069-071, Anderson Depo. pp. 61-63). Dr. Anderson also admitted that he had no evidence that **Redacted** acted as a solubility agent for the **Redacted** system in Teva's formulation. (Exhibit 14 at A067-069, Anderson Depo. pp. 59-61). Moreover, Dr. Long abandoned the use of **Redacted** because it did not provide antimicrobial properties. (Exhibit 8 at A039-041, Long. Tr. at 408-09; 445, lines 1-8). Using the testimony of Glaxo's own expert and inventor, Glaxo has failed to prove that **Redacted** performs the same functions as ethanol in the invention.

Admitting that he has no proof that Teva's Redacted has two Redacted functions, Dr. Anderson effectively admitted that Glaxo has no proof to meet its burden under *Graver Tank*. As a matter of law, Teva's Redacted formulation should be found to not be the equivalent of the patent claims because Glaxo has failed to prove a critical element of its case.

E. The *Glaxo v. Pharmadyne* Decision Is Not Binding Or Persuasive Precedent

Glaxo has had success in the past in obtaining patent protection over the use of Redacted in a ranitidine oral solution against another generic manufacturer, Pharmadyne. *See Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265 (D. Md. 1998). The *Pharmadyne* decision provides a thorough exposition of the facts (as they were known then) pertaining to Glaxo's development of the invention, the patent and its prosecution. It also found that Pharmadyne's oral ranitidine solution, which contained Redacted infringed the '249 patent under the doctrine of equivalents.

The *Pharmadyne* decision does not control this case, however. First, the decision was never appealed to the Federal Circuit. Second, the law regarding the doctrine of equivalents has changed significantly since the *Pharmadyne* decision. Both the Supreme Court and the Federal Circuit have restricted the doctrine from its expansive earlier interpretation. Finally, key evidence to this case was not before the *Pharmadyne* court. The page from Dr. Long's lab notebook showing that he foresaw the use of Redacted as a stabilizer (Exhibit 10 at A045) was not before the *Pharmadyne* court.

The doctrine of equivalents has been significantly restricted in application by the Federal Circuit since the *Pharmadyne* court's decision, especially with respect to the limitations imposed on the doctrine by prosecution history estoppel, as announced by the Supreme Court in 2002 in the *Festo* decision. 535 U.S. 722 (2002). There is no discussion in the *Pharmadyne* decision of the narrowing amendments or arguments submitted to the Patent Office by Glaxo to obtain its patent, either as it applies to claim construction or to the doctrine of equivalents.

Indeed, there appears to have been no construction of claim language by the *Pharmadyne* court at all. *Pharmadyne* at 284 ("There is no dispute as to the construction of the claims of the '249 patent."). In this case, there also is clear evidence, not presented to the *Pharmadyne* court, showing that before filing his patent application, Dr. Long foresaw the use of **Redacted** to stabilize ranitidine. (*See* Exhibit 10 at A045). This fact both limits the scope of Glaxo's patent claim, and eliminates the possibility that the doctrine of equivalents is available to Glaxo here.

Regardless, the *Pharmadyne* court's legal conclusions, premised on 1) a different accused formulation[25] 2) against a different defendant, 3) decided when the state of the law was not as it is today, and 4) predicated on an unarticulated construction of the claims, has no binding effect on this Court. *See Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1324 (Fed. Cir. 1987)("A device not previously before the court, and shown to differ from those structures previously litigated, requires determination on its own facts.") The proper application of the law and policy underlying the doctrine of equivalents mandates a different legal conclusion here, than in the *Pharmadyne* decision.

V. CONCLUSION

Glaxo's arguments and actions during the prosecution of the '249 patent would lead a person skilled in the art reasonably to conclude that Glaxo viewed ethanol as a critical component of its invention. Although Dr. Long foresaw **Redacted** as a stabilizer for ranitidine, he elected to disclose and prosecute narrowed claims specifically identifying and touting the surprising effects of only ethanol. Glaxo should not be allowed to discard that position and embrace a substitute it did not disclose to the public or claim.

[25] The accused formulation in *Pharmadyne* contained 12.5% w/v propylene glycol and 25% sorbitol in comparison to Teva's formulation with **Redacted** and **Redacted** (*Pharmadyne*, 32 F. Supp. 2d at 281; Exhibit 7 at A031)

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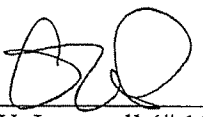

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CERTIFICATE OF SERVICE

I, Adam W. Poff, Esquire, hereby certify that on July 10, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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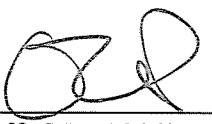

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